Research Article

A RANDOMIZED COMPARATIVE CLINICAL TRIAL TO EVALUATE THE EFFECT OF *KUSTHADI LEPA* AND *JALAUKAVACHARANA* ALONG WITH *MANJISHTHA CHURNA* IN *YUVANPIDAKA*

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ABSTRACT

Face is the most important organ is affected by curtained anomalies in adolescent age i.e., 16-30 years and commonest anomaly which disfigures the face in youth is Acne vulgaris. Acne is major problems at the puberty age. Acne vulgaris affects 85% of young adults aged 12–25 years and is one of the top three most common skin disorders in general populations. Symptomatology of acne vulgaris resembles with *Yuvanpidaka*. *Manjistha Churna, Kusthadi Lepa* and *Jalaukavacharana* was taken and effort was made to see the effectiveness of these all drugs in the management of *Yuvanpidaka*. **Aim:** To evaluate the role of *Kusthadi Lepa* and *Jalaukavacharana* along with *Manjishtha Churna* in *Yuvanpidaka*. **Materials and Methods:** Present clinical study was a randomized comparative trial for the management of *Yuvanpidaka*. Total 40 patients were enrolled and divided into two groups. *Manjistha Churna* with *Kusthadi Lepa* and *Manjistha Churna* with *Jalaukavacharana* were given to 20-20 patients of Group A and Group B respectively for duration of 30 days. Patients were assessed by clinical signs and symptoms of *Yuvanpidaka*. Statistical analysis was carried out by Software: In Stat Graph Pad 3 (version 3.10). **Results:** Highly significant results were found on Group B comparison to Group A on both subjective and objective parameters. **Conclusion:** The study revealed that both the drugs have significant effects but Group B shown higher significant results compare to Group A in the management of *Yuvanpidaka*. So it can conclude that both the drugs can be used for *Yuvanpidaka*.

INTRODUCTION

Face is a window of body and mind. Face is affected by curtained anomalies in adolescent age i.e. 16-30 years and the commonest anomaly which disfigures the face in youth is acne vulgaris/ *Yuvanpidaka*. The vitiation of *Pitta* located in the skin leads the manifestation of *Pidaka*[1]. *Acharya Sushruta* mentioned *Yuvanpidaka* as *Mukhadusika* in the group of *Kshudra Roga*[2]. *Acharya Charaka* described *Yuvanapidaka* in *Raktapradoshaja Vikara*[3]. The eruptions in *Yuvanpidaka* is looked like *Kantaka* of *Shalmali* and caused by *Kapha, Vata Dosha* and *Rakta Dushya*[4].

Acne or acne vulgaris found to have parity with the diseases of *Yuvanpidaka*. It is in acute or chronic form, inflammatory or non-inflammatory diseases of the pilosebaceous units of the skin with formation of a papules or pustules eruption[5]. It mostly affects the skin of face involving cheeks, chin, nose and foreheads.

Acne is major problems at the puberty age. Acne vulgaris affects 85% of young adults aged 12–25 years, according to the Global Burden of Disease (GBD)[6] study and is one of the top three most common skin disorders in general populations. Prevalence data available from USA, EU, New Zealand and Australia showed that Acne affects 80% of people between the ages of adolescence and thirty of age[7]. Acne is curable very easily if treatment is done on time but if it is not treated in proper time then it might be give rise to complication like scars, disfiguring, cysts, nodules, keloids and major psychiatric depression and so on. For its treatment various systems of medicines come up with various remedies and therapeutics

procedures. The treatment may starting from simple topical application to extensive management like use X-rays, multi-vitamins, corticosteroids, different antibiotics, hormone therapy etc. The results from all these procedures possess temporary relief, limitation and several health hazards on the body.[8]

Regarding the treatment for *Yuvanapidaka*, there are many procedures and external applications has mentioned in Ayurvedic classics. Ayurvedic treatment is conduct in two ways i.e., *Shamana Chikitsa* and *Sodhana Chikitsa. Shamana Chikitsa* includes *Prakshalana, Abhyanga, Lepana, Udvartana* and internal medicine etc. while *Sodhana Chikitsa* includes *Vamana, Virechana, Nasya, Rakta Mokshana* etc. *Acharya Sushruta* has advised *Lepa, Sodhan* therapy, *Siravedha Karma* in *Yuvanpidaka* while *Acharya Vagbhata* recommends *Lepa* and *Raktamokshan* in its treatment. The first selected trial drug was *Manjistha* and is mentioned in *Varnya Mahakashaya[9].* The second selected trial drug was *Kusthadi Lepa* consists of *Dhanyak, Vacha, Lodhra* and *Kustha[10].* The third one was *Jalaukavacharana[11]* and the effort was made to see the effectiveness of these all drugs in the management of *Yuvanpidaka.*

AIM AND OBJECTIVES

Aim

To evaluate the role of *Kusthadi Lepa* and *Jalaukavacharana* along with *Manjishtha Churna* in *Yuvanpidaka.*

Objectives

- To evaluate the efficacy of *Manjistha Churna* and *Kusthadi Lepa* in *Yuvanpidaka.*
- To evaluate the efficacy of *Manjishtha Churna* and *Jalaukavacharana* in *Yuvanpidaka.*
- To compare the efficacy of *Kusthadi Lepa* and *Jalaukavacharana* along with *Manjistha Churna* in *Yuvanpidaka.*

MATERIAL AND METHOD

To explain fundamental principles, references were collected from classical Ayurvedic texts as well as earlier research works, peer-reviewed journals, thesis, dictionaries, research publications, review articles, reference works and contemporary medical science text book.

The study got approved by Institutional Ethics Committee (no: IEC/ACA/2020/3-43), dated 30th June, 2020 and trial was registered in Clinical Trial registry of India (Reg. No. CTRI/2021/04/032883 dated: 16th April, 2021. Patients visiting the outpatients

department of *Aragyoshala* N.I.A. Hospital and were thoroughly examined for clinical sign and symptoms of *Yuvanpidaka* along with the necessary hematological and biochemical investigations. Subjects were enrolled for the study considering the criteria of inclusion, after getting the consent. The registered patients were allocated into two groups namely Group A and Group B, using the randomization sheet (made by computer method of randomization). Each group had 20 patients.

For Group A- *Manjishtha Churna* (orally 3gm twice daily, before meal with lukewarm water) with *Kusthadi Lepa* (external application, once daily) had given for 30 days.

For Group B- *Manjishtha Churna* (orally 3gm., twice daily, before meal with lukewarm water) with 4 sittings of *Jalaukavacharana* with 7 days interval had given for 30 days. After completion of the clinical trial, the patients were followed up for further 15 days.

Inclusion Criteria: Patient willing to undergo trial and ready to give informed consent (in case of minor patients, i.e., age <18 years, consent will be given by parents/guardian/attendant), patient in the age group of 16-40 years, patient with sign and symptoms of *Yuvanpidaka* and patient fit for *Jalukavacharana.*

Exclusion Criteria: Known case of any acute/chronic skin diseases like psoriasis, vitiligo, dermatitis etc., known case of any genetic skin disorder, chronic systemic diseases, sexually transmitted disease, diabetes mellitus, hypertension, any blood disorders or any organ failure.

Withdrawal Criteria: During the course of trial, if any serious condition or any serious adverse effects appears which requires urgent treatment, patient himself/herself wants to withdraw from the clinical trial.

Diagnostic Criteria: The patients who had registered for the trial were thoroughly assessed in accordance with the clinical trial performa as well as modern aspect of signs and symptoms.

Criteria of Assessment: Drugs and procedure were given to the patients for 30 days. The changes in classical sign and symptoms were recorded after 15 days and after 30 days. The effect of trial drug was assessed on following criteria.

I) On the basis of classical Sign and Symptoms- *Pidaka* (eruption), *Kandu* (itching), *Ruja* (pain), *Daha* (burning sensation), *Shrava* (discharge), *Snigdhata* (unctuous) and *Vaivarnya* (black scars).

Gradation Assessment Criteria

The following Gradational Assessment Criteria was considered for the study (This criterion was based on grading of subjective parameters).

1. *Pidaka* (Eruption)		
1.	No eruption in the lesion	0
2.	Scanty eruption in few lesion	1
3.	Scanty eruption in at least half of the lesion	2
4.	All the lesions full of eruption	3
2. *Kandu* (Itching)		
1.	No itching	0
2.	Often mild type of itching (1 -2 times in a day)	1
3.	Moderate itching along with episodes (3 – 4) times in a day	2
4.	Severe itching episodes more than 5 times a day even night and blood spot come out	3
3. *Ruja* (Pain)		
1.	No pain	0
2.	Pain on deep pressure	1
3.	Pain on mild pressure	2
4.	Continuous pain without touching	3
4. *Daha* (Burning sensation)		
1.	No burning sensation even after rubbing	0
2.	Mild type of burning sensation, sometimes and not disturbing normal activity.	1
3.	Moderate type of burning sensation	2
4.	Severe burning sensation disturbing normal activity	3
5. *Shrava* (Discharge)		
1.	No discharge	0
2.	Watery discharge	1
3.	Whitish discharge	2
4.	Yellowish discharge	3
6. *Snigdhata* (Unctuous)		
1.	No oily face	0
2.	Face becomes oily 3-4 hours after face wash	1
3.	Face becomes oily 1-2 hours after face wash	2
4.	Require face wash frequently	3
7. *Vaivarnya* (Black scars)		
1.	No acne scars	0
2.	1-5 scars	1
3.	6-10 scars	2
4.	More than 10 scars	3

II) Global Acne Grading System (GAGS)

Global Acne Grading System Work Sheet

Location	Factor(F)	Severity(S)		Local score (F*S)	Acne severity	
Forehead	2					
Right cheek	2	0	Nil		Mild	1-18
Left cheek	2	1	Comedones		Moderate	19-30
Nose	1	2	Papules		Severe	31-38
Chin	1	3	Pustules		Very severe	>39
		4	Nodule			
Chest and upper back	3					
		Total score				

Grade 0- No lesions; 1 ≥ one comedone; 2 ≥ one papule; 3 ≥ one pustule; 4 ≥ one nodule

All these criteria of baseline data to post-medication data had been compared for clinical assessment of the results. The objective parameters include Complete blood count and ESR.

Statistical Analysis: All the Results were calculated by using Software: In Stat Graph Pad 3 (version 3.10).

OBSERVATION

The registered patients (out of total 40, all 40 patients completed the treatment) were allocated into two groups. In Group A *Manjistha Churna* along with *Kushthadi Lepa* was given and all 20 patients were registered and completed also. While in group B *Manjistha Churna* along with *Jalaukavachrana* was given and all 20 patients were registered and completed also.

Maximum number of patients were in the age group of 16-20 years (42.50%), male (5.50%), unmarried (82.50%), Hindu (95.00%), middle economic class (35.00%), urban area (42.50%), undergraduate (52.50%), students (92.50%), from *Sadharana Desha* (57.50%), having family history (22.50%), vegetarian (67.50%), addicted to tea/coffee (65.00%), aggravation was maximum seen in winter season (30.0%) followed by in summer season (22.50%), oily skin type (47.50%), irregular/ constipated bowel habit (67.50%), *Kapha-Vata Prakriti* (47.50%), having *Manda Agni* (42.50%), *Avara Ahara Shakti* (52.50%), had *Krura Kostha* (42.50%), *Prabhuta Nidra* (35.00%), *Madhyama Satva* (45.00%), *Kalaj Nidan* (42.50%), *Madhura Rasa* predominant (40.00%), *Pidaka* was more on bilateral cheeks (40.00%), 6-10 *Pidakas* on face (45.00%) and 15 subjects (37.50%) had not taken any type of treatment.

RESULTS

All the Results were calculated by using software: In Stat Graph Pad 3 (version 3.10). For non-parametric Data - Wilcoxon matched-pairs signed ranks test was used while for Parametric Data - Paired 't' Test was used for the calculation of results in each group. For inter group comparison - Mann-Whitney Test and Unpaired 't' Test was used. The values were considered significant at the levels of $P < 0.05$

Intragroup Analysis

Analysis of Subjective Parameters

Table 1: Showing effect of treatment on Subjective Parameters of both groups (Wilcoxon Matched Pairs Single Ranked Test)

Symptoms	Group	Mean		Mean Diff.	% of Change	SD±	SE±	p value	R
		BT	AT						
Pidaka number	**Group A**	1.5	0.95	0.55	36.67	0.60	0.14	0.0020	VS
	Group B	2.0	0.75	1.25	62.5	0.71	0.16	<0.0001	ES
Kandu	Group A	0.9	0.50	0.40	44.44	0.50	0.11	0.0078	VS
	Group B	1.35	1.05	0.3	22.0	0.47	0.10	0.0313	S
Ruja	Group A	1.45	1.00	0.45	31.03	0.51	0.11	0.0039	VS
	Group B	1.4	0.95	0.45	32.14	0.51	0.11	0.0039	VS
Daha	Group A	0.75	0.40	0.35	46.67	0.49	0.11	0.0039	S
	Group B	0.95	0.25	0.7	73.68	0.80	0.17	0.0020	VS
Shrava	Group A	2.25	1.65	0.60	26.67	0.50	0.11	0.0005	ES

	Group B	2.95	0.6	2.35	79.66	0.48	0.10	<0.0001	**ES**
Snigdhata	Group A	1.2	0.75	0.45	37.50	0.60	0.14	0.0078	**VS**
	Group B	1.95	1.45	0.50	25.64	0.51	0.11	0.0020	**VS**
Vaivarnya	Group A	1.75	1.45	0.30	17.14	0.47	0.11	0.0313	**S**
	Group B	2.20	1.80	0.40	18.18	0.50	0.11	0.0078	**VS**
GAGS Score	Group A	12.60	10.85	1.75	13.89	0.72	0.16	<0.0001	**ES**
	Group B	18.10	7.6	10.5	58.01	2.78	0.62	<0.0001	**ES**

Intergroup Analysis
Subjective Comparison

Table 2: Intergroup Comparison in Subjective Parameters of Group A and B (Mann-Whitney Test)

Symptoms	Group	(AT-BT) Diff. mean	SD±	SE±	Man Whitney Value (U')	P Value	R
Pidaka number	A	0.55	0.60	0.135	301.50	0.0033	**VS**
	B	1.25	0.71	0.16			
Kandu	A	0.40	0.5026	0.1124	220.00	0.5233	**NS**
	B	0.30	0.4702	0.1051			
Ruja	A	0.45	0.51	0.114	200.0	0.9875	**NS**
	B	0.45	0.51	0.114			
Daha	A	0.35	0.4894	0.1094	244.00	0.1814	**NS**
	B	0.70	0.8013	0.1792			
Shrava	A	0.60	0.5026	0.1124	400.00	<0.0001	**ES**
	B	2.35	0.4894	0.1094			
Snigdhata	A	0.45	0.6048	0.1352	215.00	0.6522	**NS**
	B	0.50	0.5130	0.1147			
Vaivarnya	A	0.30	0.4702	0.1051	220.00	0.5233	**NS**
	B	0.40	0.5026	0.1124			
GAGS Score	A	1.75	0.7164	0.1602	400.00	<0.0001	**ES**
	B	10.500	2.782	0.6220			

Intergroup Comparison on Subjective Parameters of Both Groups

Table 3: Showing the % relief in both the groups in Subjective Parameters

Subjective Parameters	% Relief in Group A	% Relief in Group B
Pidaka number	42.50%	67.05%
Kandu	41.67%	55.75%
Ruja	33.34%	59.60%
Daha	50.14%	70.83%
Shrava	32.68%	80.02%
Snigdhata	39.28%	37.55%
Vaivarnya	27.75%	46.63%
GAGS Score	33.02%	63.65%

BT – Before Treatment; **AT** – After Treatment; **Diff**. – Difference; **SD** – Standard Deviation; **SE** – Standard Error; **R** – Results; **ES** – Extremely Significant; **VS** – Very Significant; **S** – Significant; **NS** – Non Significant; **p-value** – Probability Value; **GAGS** – Global Acne Grading System

DISCUSSION

Abnormalities in the skin are always more troublesome for humans beings than any other diseases. *Yuvanpidaka* is one disorder which affects natural beauty of the skin. In present study, *Kusthadi Lepa* and *Jalaukavacharana* were used as a local application and *Manjistha Churna* as internal administration. The therapeutic effect of a drug mainly depends on its pharmacodynamics properties viz. *Rasa*, *Guna*, *Virya*, *Vipaka* and *Prabhava*. A drug performs its actions partially due to *Rasa*, partially due to *Guna*, partially due to *Virya* and so on.

On **number of *Pidaka* (comedones, papules, nodules)** - **Extremely Significant** results was seen on **Group B** followed by very significant in **Group A**. Drugs having *Madhura Rasa, Ushna Virya* and *Singdha Guna* (*Dhanyaka*) normalized the vitiated *Vata Dosha*, by having the *Tikta, Katu Rasa (Vacha, Kustha)* and *Ushna Virya* it normalized the vitiated *Kapha Dosha* and by having the *Madhura, Tikta* and *Kashaya Rasa (Dhanyaka, Manjistha)* causes *Kleda Meda Upashoshana.* Also the Eglin, Gelin, Eglin C, Tryptase, complement C_1 inhibitor, hyaluronidase etc. which are found in saliva of leech inhibit the inflammation and had anti-oxidant properties. The research finding of these used medicine like antioxidant, anti-bacterial, anti-microbial, anti-acne activity, anti-inflammatory property etc. also helps in decreased the number of *Pidaka*.

On ***Kandu*** and ***Snigdhata*** **(itching sensation & unctuous)** - **Very Significant** results was seen on both groups. The presence of *Tikta* and *Kashaya Rasa (Dhanyaka, Manjistha), Katu Vipaka (Kustha, Manjistha)* and *Ushna Virya (Kustha, Manjistha)* subsided the *Kledata* of *Kapha* and reduced *Snigdhata* of face. The presence of *Ama* due to vitiated *Kapha* was digested by *Tikta* and *Kashaya Rasa. Ushna Virya* and *Katu Vipaka* of the drugs reduced the *Kandu. Vacha* restores the malfunction of *Bhrajaka* and *Ranjaka Pitta*.

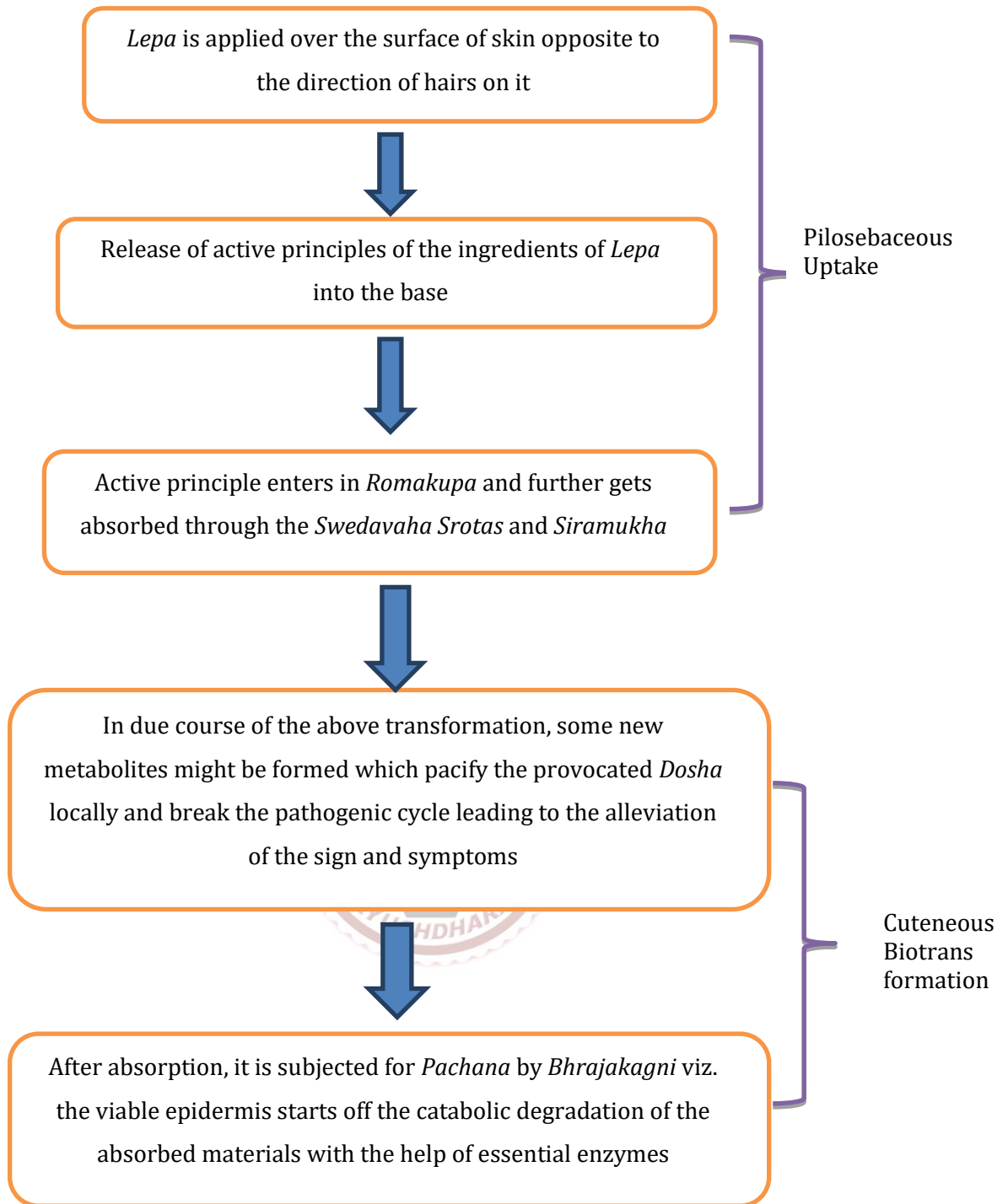On ***Ruja*** **(Pain)** - **Very Significant** results was seen on both groups. *Katu Vipaka (Manjistha, Vacha, Lodhra, Kustha)* and *Usna Virya (Manjistha, Kustha, Dhanyaka, Vacha)* of the drug reverse the obstruction by dissolution of vitiated *Kapha* and cleansing the *Srotas. Madhura Rasa, Snigdha Guna (Dhanyaka)* of the drug subside the vitiated *Vata Dosha.* Thus it relieves the intensity of pain. Also leech saliva contains powerful anesthetic enzymes hirustatin which help in reduced the pain.

On ***Daha*** **(Burning sensation)** - **Very significant** results was seen on Group B and **Significant** results was seen on Group A. *Madhura Rasa (Dhanyaka)* does *Kshina Kshata Sandhankara Karma* which reduced *Daha. Sheeta Virya* of *Vacha* causes *Shitaprasamana* on *Daha. Pittahara* property of *Manjistha* pacifies the *Daha* of acne.

On ***Srava*** **(Pustules, Discharge)** - **Extremely Significant** results was seen on both groups. The drug digests the *Ama* by its *Ushna Virya (Manjistha, Dhanyaka, Vacha, Kustha)* and *Katu Vipaka (Vacha, Lodhra, Kustha)* and helped in reducing *Srava*. Also due to the *Ruksha, Laghu Guṇa (Manjistha, Lodhra, Kustha)* and *Tikta Rasa (Kustha, Vacha)* of the drugs subside the *Kledata* of *Kapha* and *Snigdhata* of *Pitta Dosha*. Thus it declines the *Srava* (pustules) of *Yuvanpidaka*.

On ***Vaivarnya*** **(Black Scar) -** **Very Significant** results was seen on Group B and **significant** results was seen on Group A. *Madhura Rasa* of *Dhanyaka* is *Kshina Kshata Sandhankara* which improves wound healing, reduces *Vranavastu. Laghu* and *Ushna Guna (Dhanyaka*) cause *Varna Ropana Karma* and *Vata Shamana. Lodhra* have a *Varnaropaka* property which promotes faster healing of lesions without leaving scars. Manjisthin, purpurine along with resins showed a *Varṇya, Rakta Prasadhak, Rakta Sodhak* properties. Methanolic extract of *Manjistha* has been reported to show 14.80% mean inhibition of tyrosinase activity thereby acting as skin whitening agent[12]. The probable mode of action of *Lepa* can be described as follows-

Lepa is applied over the surface of skin opposite to the direction of hairs on it

⬇

Release of active principles of the ingredients of *Lepa* into the base

⬇

Active principle enters in *Romakupa* and further gets absorbed through the *Swedavaha Srotas* and *Siramukha*

Pilosebaceous Uptake

⬇

In due course of the above transformation, some new metabolites might be formed which pacify the provocated *Dosha* locally and break the pathogenic cycle leading to the alleviation of the sign and symptoms

⬇

After absorption, it is subjected for *Pachana* by *Bhrajakagni* viz. the viable epidermis starts off the catabolic degradation of the absorbed materials with the help of essential enzymes

Cuteneous Biotrans formation

Flow chart 2: Probable mode of action of *Lepa* in *Yuvanpidaka*

Effect of Treatment on Group A

Before Treatment

After Treatment

Effect of Treatment on Group B

Before Treatment

After Treatment

CONCLUSION

Yuvanpidaka is a skin disease which is mentioned in various Ayurvedic texts under the heading of *Kshudra Roga*. Its prevalence is more in the *Youvana* stage of *Madhyama Vaya.* A number aggravation factors for *Yuvanpidaka* have been identified viz., *Aharaj* and *Viharaj* factors, taking of unwholesome diet, improper *Agni*, irregular bowel habits, disturbed sleep pattern, excessive use of *Madhura, Amla* and *Lavana Rasa*, over use of cosmetics items etc. *Snigdhata* over face is the most common type of associated complaint seen in maximum number of patients followed by *Paka, Srava, Sotha. Kandu, Daha,* and *Vaivarnya*. The local applications - *Kusthadi Lepa* which constitutes four ingredients viz., *Dhanyaka,*

Vacha, Lodhra, Kustha and a single drug *Manjistha Churna* showed effective results in relieving the sign and symptoms of *Yuvanpidaka*. Also, *Jalaukavacharana* is very effective in relieving the associated symptoms. Percentage of relief on both subjective and objective parameters was higher in Group B (61.25%) compared to group A (39.82%). That means effectiveness of therapy was more in Group B in comparison to Group A.

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